

U54 Cancer Health Disparities and Minority Health (CHD-MH) SPORE Program Concept

NCI Translational Research Program &
Center to Reduce Cancer Health Disparities

NCI SPORE Program

- Multi-project specialized P50 center grants for translational cancer research ([PAR-20-305](#)).
- Contributes to improved prevention, early detection, diagnosis, and treatment of cancer.
- SPOREs can focus on any of the following:
 - An organ-specific cancer
 - A group of highly related cancers (e.g., sarcoma, GI, neuroendocrine)
 - Cancers related by common biological pathway mutations/alterations or other cross-cutting themes, such as pediatric cancers, virally-related cancers, or **cancer health disparities**.

Cancer Health Disparities Research

- **Cancer health disparities (CHD) is a [priority research](#) area for the NIH and NCI**
 - NIH-Wide Strategic [Plan](#)
 - NIH Minority Health and Health Disparities Strategic [Plan](#)
 - National Cancer [Plan](#) and NCI Equity and Inclusion [Program](#)
- **Despite many applications, [no P50 SPOREs](#) specifically focused on CHD have been awarded.**

CHD Research Gap in SPORE Portfolio

- To address the CHD research gap in the SPORE portfolio, a **P20 Cancer Health Disparities SPORE RFA** was developed in 2017.
- The P20 CHD SPORE Program **supported twelve planning grants** focused on building feasibility and infrastructure to:
 - Evolve into comprehensive translational research programs
 - Be competitive for awards as full SPORE (P50) grants
- Initial program analysis indicates success in the P20 CHD SPORE Program meeting its goals.
- However, the **CHD funding gap in the P50 SPORE portfolio remains**, despite twelve P50 SPORE CHD applications from the P20s and other applicants.

NCI CHD Portfolio Analysis

- In QVR, 290 NCI awards* from FY2018 to the present included RCDC Index Concepts for CHD:
 - Only 19 of the 290 NCI awards (7%) focused on translational research in CHD (\$21.5M total).
 - All 19 grants were from the P20 SPORE Program (12 total) and the PACHE Program (7 total).
- In QVR, 87 NCI awards* from FY2018 to the present included Minority Health RCDC Index Concepts:
 - No NCI awards focused on translational minority health research.
 - 40 R01, 10 R21, 1 P01, 5 P20, 5 P50, 8 U01, and 18 U54 totaling \$81.4M.

P50 SPORE CHD Research Gap: Contributing Factors

- The requirements of the P50 SPORE **cannot fully address** the unique needs, methodology, and framework of CHD:
 1. SPORE (P50) PAR focuses specifically on the mechanistic aspects of the **biology of human cancer**, while CHD requires a multi-faceted approach addressing the interplay of social, cultural, and environmental factors with the biology of the disease.
 2. SPORE (P50) PAR requires at least one project to include an **NIH-defined clinical trial**, which is a major disadvantage for CHD SPORE applications in peer review given that it is extremely difficult to prospectively accrue large enough numbers of patients from populations who are underserved to assess statistically significant differences in patient outcomes.

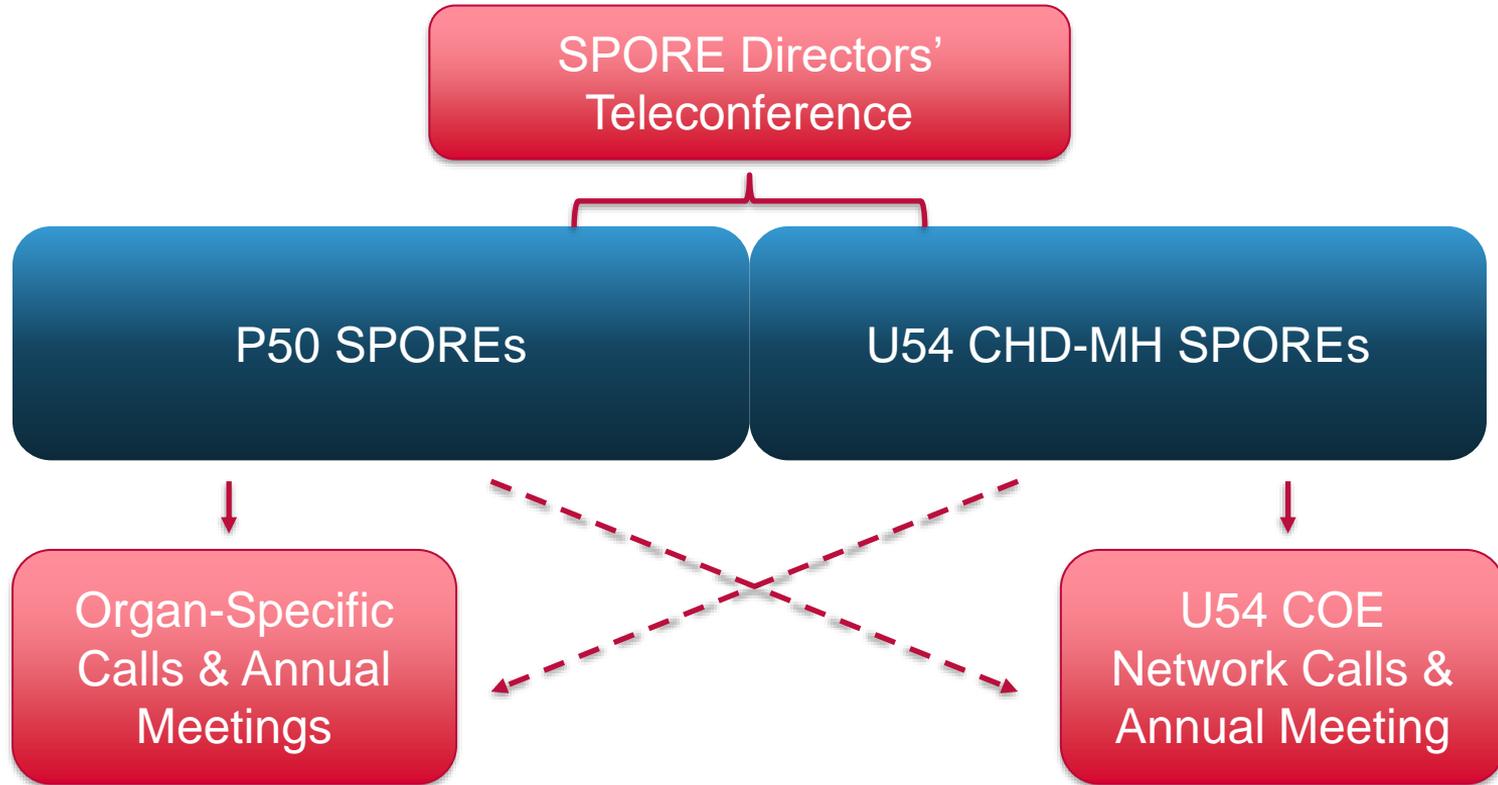
U54 Cancer Health Disparities and Minority Health SPORE Program

- To appropriately address the unique needs of CHD and minority health translational research would require **significant levels of community outreach, engagement, and collaboration** that does not fit within the scope of a P50 program.
- Therefore, an RFA is proposed for a **U54 Cancer Health Disparities and Minority Health (CHD-MH) SPORE Program**:
 - U54 CHD-MH SPOREs would join the P50 SPOREs in NCI TRP
 - Support CHD and minority health **translational research** in populations who are underserved

SPORE Components Comparison

	P50 SPORE	U54 CHD-MH SPORE
Minimum 3 Translational Research Projects	Yes	Yes
Administrative Core	Yes	Yes
Biospecimen/Pathology Core	Yes	Yes
Scientific Collaborations	Yes	Yes
Developmental Research Program (DRP)	Yes	Yes
Career Enhancement Program (CEP)	Yes	Yes
Community Outreach and Engagement (COE) Core	No	Yes
Budget Cap	\$1.4M DC	\$1.6M DC
NIH-Defined Clinical Trial	Yes	Optional
Human Endpoint (in each Project)	Yes	Yes, including pilot/feasibility studies
Community Advisory Board	No	Yes
Project Co-Leadership (Basic and Applied)	Yes	Yes, including epidemiologists and social scientists

SPORE Interactions to Foster Collaboration



U54 CHD-MH SPORE Program: Scientific Focus

- **U54 CHD-MH SPOREs scientific focus:**
 - Cross-cutting theme of translational CHD and/or minority health research with the option to investigate more than one cancer type in populations who are underserved.
- **Projects may address, but are not limited to, the following areas of investigation:**
 - Discovery, validation, and assessment of how various determinants of health intersect with the biology of cancer to affect cancer incidence, diagnosis, treatment, early detection, and prevention in populations who are underserved.
 - Characterization of the biological impact of social determinants of health and identifying specific biological pathways that might be targeted by clinical or public health interventions.
 - Hypothesis generating studies characterizing risk factor prevalence or biological differences in populations who are underserved.
 - Understanding the role of determinants of health and comorbidities on toxicity to therapeutic interventions in populations who are underserved.

Budget

- **Up to six (6) U54s will be awarded with a five-year project period.**
 - Two receipt dates per year for two years, funding up to three (3) awards per year.
- **Each U54 will be a maximum of \$1.6M DC (or ~\$2.7M TC) per year including the \$25k DRP Project Incentive (if elected).**
 - Three (3) U54s per year are estimated at \$4.9M DC (or ~\$8.0M TC).
- **Total U54 CHD-MH SPORE Program cost for six (6) five-year grants is estimated at \$48.8M DC (or ~80.4M TC):**

FY25

Year 1 TC	Year 2 TC	Year 3 TC	Year 4 TC	Year 5 TC	Year 6 TC	Total Program Cost
\$8,043,750	\$8,043,750	\$8,043,750	\$8,043,750	\$8,043,750	\$0	
	\$8,043,750	\$8,043,750	\$8,043,750	\$8,043,750	\$8,043,750	
\$8,043,750	\$16,087,500	\$16,087,500	\$16,087,500	\$16,087,500	\$8,043,750	\$80,437,500

Evaluation

- **U54 CHD-MH SPORE Program metrics of success will include:**
 - Development of novel interventions, methodologies, and metrics for advancing CHD and minority health research.
 - Increase research in populations who are underserved and underrepresented in the NCI portfolio.
 - Increase enrollment of populations who are underserved in clinical trials.
 - Establishment of U54 CHD-MH SPORE Community Outreach and Engagement (COE) Cores that are integrated and interface with NCI-Designated Cancer Center COEs.
 - Proposed human endpoints achieved within project period.
 - Publications and citations from U54 CHD-MH SPORE grants.

BSA Reviewer Comments

- **Describe what success of the CHD-MH SPORE Program will look like.**
 - Bringing in a new network of CHD and MH investigators to the SPORE portfolio
 - Establishing a Special Emphasis Panel peer review for CHD and MH translational research
 - Introducing and integrating CHD-MH research, resources, and collaborative opportunities to the entire SPORE program
 - Sustainable and long-lasting community engagement beyond the 5 years of the grant
- **How will the CHD-MH SPORE program support diversity of the investigators on the grant?**
 - A required Plan for Enhancing Diverse Perspectives (PEDP) must be included in the Administrative Core.
 - Strategies for recruitment of investigators from underrepresented backgrounds must be described in the Career Enhancement Program (CEP).
 - Additional Developmental Research Program (DRP) funding to support projects led by investigators from underrepresented backgrounds

BSA Reviewer Comments

- **How will the COE Core and Community Advisory Board (CAB) be differentiated? Will they leverage what is existing at the institution/cancer center?**
 - In the SPORE mechanism, shared resources cores leverage, augment, and integrate with existing core resources.
 - The CAB activities will be advisory and focused on evaluation of the COE and U54 research in meeting the needs of the community and cancer patient population in the catchment area.
 - The COE will build and sustain partnerships to engage with the community and help investigators implement evidence-based interventions to address factors influencing cancer burden, clinical trial enrollment, access to care, etc. in the community.
- **Demonstration of partnership in the COE Core is essential.**
 - Yes, applicants must demonstrate effective ongoing collaborations, partnerships, engagement with the community, efforts to promote sustainability of the COE efforts, and plans for shared governance or non-hierarchical/equitable input from community members and stakeholders.

BSA Reviewer Comments

- **Can the translational component include population science?**
 - Yes, the SPORE program strongly encourages and incentivizes population science projects and human endpoints. This will be part of the U54s as well.
- **How is the data science approach addressing its own approach to science, to its own bias?**
 - The RFA will encourage investigators to incorporate measures addressing bias in the data science approach, including data collection and interpretation.
- **It will be critical to highlight the role of genetic ancestry, geographic origin, and social determinants of health in driving disparities.**
 - The RFA will encourage applications investigating the impact of various determinants of health on disparities, specifically genetic ancestry, geographic origin, and social determinants of health.



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